

Message

From: Schaible, Stephen [Schaible.Stephen@epa.gov]
Sent: 6/23/2020 7:50:11 PM
To: Rice, Denise [Rice.Denise@epa.gov]
CC: Katz, Brian [Katz.Brian@epa.gov]; Messina, Edward [Messina.Edward@epa.gov]
Subject: FW: Senate Committee on Environment and Public Works: Follow up Questions for Witness, Administrator Wheeler

Hi Denise,

This question below from Sen. Cramer is in regard to whether EPA would be able to issue FIFRA GLP certificates, and is among the Questions for Response from the SEPW.

10. EPA has a premier audit and inspection program for Good Laboratory Practices (GLPs), recognized worldwide. However, EPA does not issue certificates of GLP compliance for laboratories, as other nations do, that would make it easier for many regulatory authorities in countries around the world to recognize the GLP credentials of regulatory studies conducted in the US. This places US contract research laboratories and US businesses at an economic and competitive disadvantage in seeking product marketing approvals in those countries and exporting their products and services. EPA has recently received additional funding from PRIA4 to enhance the GLP program. What specific changes to US regulations and/or legislation would be necessary to allow/require EPA to issue such GLP certificates? What changes could be made under President Trump's May 19, 2020 Executive Order 13924 on economic recovery from COVID-19 to accomplish this?

Ex. 5 Deliberative Process (DP)

Steve

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From: Schaible, Stephen
Sent: Thursday, June 11, 2020 6:02 PM
To: Katz, Brian <Katz.Brian@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>
Cc: Vizard, Elizabeth <Vizard.Elizabeth@epa.gov>
Subject: FW: Senate Committee on Environment and Public Works: Follow up Questions for Witness, Administrator Wheeler

Hi all,

Ex. 5 Deliberative Process (DP)

Steve

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From: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>

Sent: Wednesday, June 10, 2020 11:30 AM

To: Nguyen, Khanh <Nguyen.Khanh@epa.gov>; Kochis, Daniel <Kochis.daniel@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Schaible, Stephen <Schaible.Stephen@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Levine, Carolyn <Levine.Carolyn@epa.gov>

Subject: RE: Senate Committee on Environment and Public Works: Follow up Questions for Witness, Administrator Wheeler

SEPW QFR team – OECA asks to be involved in the drafting of the response to Cramer 10 on GLP. OECA's Office of Compliance is initiating a response and will coordinate with OCSPP to address possible changes to the rule/legislation necessary. Please let me know any questions.

10. EPA has a premier audit and inspection program for Good Laboratory Practices (GLPs), recognized worldwide. However, EPA does not issue certificates of GLP compliance for laboratories, as other nations do, that would make it easier for many regulatory authorities in countries around the world to recognize the GLP credentials of regulatory studies conducted in the US. **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Thanks,
Sven

Sven-Erik Kaiser
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From: Kaiser, Sven-Erik

Sent: Tuesday, June 09, 2020 6:38 PM

To: Nguyen, Khanh <Nguyen.Khanh@epa.gov>; Kochis, Daniel <Kochis.daniel@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Schaible, Stephen <Schaible.Stephen@epa.gov>; Kadeli, Lek <Kadeli.Lek@epa.gov>; Tyler, Tom <Tyler.Tom@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>

Subject: Senate Committee on Environment and Public Works: Follow up Questions for Witness, Administrator Wheeler

OCSPP Budget Team – attached are QFRs following the May 20 SEPW budget hearing. Please send responses to OCIR by **COB July 8**. OCSPP lead responses are highlighted, please let me know if need to change any assignments. Thanks,
Sven

Barrasso

1. OAR [OGC follow up review] (10th Circuit SRE decision)
2. ORD (IRIS)
3. ORD (science transparency rule)

Capito

4. OAR (ACE Rule)
5. OW (aluminum water quality standard)
6. OAR (RFS)

Cramer

7. OAR (SIP flexibilities)
8. OW [OAR follow up review] (401)
9. OW [OGC follow up review] (conduit, *Maui* decision)

10. OCSPP [OAR/ORD follow up review] (GLP)
11. OCSPP (FIFRA export certificates)

Braun

12. OAR (biogenic CO2)
13. OAR (biogenic CO2)
14. OECA [OAR follow up review] (Memo 1—mobile source air enforcement)
15. OAR (HFCs)
16. OAR (biointermediates)

Wicker

17. OW (SDWA electronic utility notices)

Ernst

18. OAR (biogenic CO2)
19. OAR (WARM model for biogenic CO2)
20. OAR (E15)
21. OAR (E15)
22. OAR (RFS)

Carper

- 23(a). OP. (EJ and COVID-19 risk factors)
- 23(b). ORD [OAR/OP follow up review] (ORD Air Climate and Energy Center research)
- 24(a). OP [OAR/OECA follow up review]
- 24(b). OP [OAR follow up review]
25. OECA [OP follow up review] (COVID-19 regulatory modifications and enforcement waivers)
26. OMS (COVID reopening)
- 27(a). OP, OECA (EO on Regulatory Relief to Support Economic Recovery, May 19, 2020)
- 27(b). OP
- 28(a-f). OAR [Oversight follow up review] (Wood heaters rule)
- 28(g-i). OAR [OECA follow up review] (Wood heaters rule)
- 28(j). OAR (Wood heaters rule)
29. OP (EO 13891 on guidance documents)
- 30(a). OGC [AO/OCIR follow up review] (retaliation)
- 30(b). OCSPP [AO/OCIR follow up review] (PFAS SNUR)
31. OLEM (PFAS hazardous substance designation)
32. Oversight (oversight letters from Doug QFRs)
33. Oversight (Doug QFR on EAB rule document request)
34. Oversight (Calendar posting on website)
35. OECA (DTE Consent Decree)
36. OLEM (coal ash groundwater monitoring)
37. OLEM (coal ash risk assessment)
38. OLEM (CCR rule)
39. OLEM [OITA follow up review] (CCR on Indian lands)
40. OLEM (CCR enforcement)
41. OLEM [OGC follow up review] (CCR court order)
42. OLEM (coal ash legacy impoundments)
43. OLEM [OP follow up review] (EJ review and CCR rule)
44. OLEM [OP follow up review] (EJ review and CCR rule)
45. OW [OGC follow up review] (powerplant wastewater; fifth circuit decision)
46. OECA (Enforcement staffing and spending)
47. OCSPP (TSCA)
48. OAR (CAA 110 good neighbor implementation)
49. OAR (RFS pathways)
50. OAR [SABSO/ORD follow up review]
51. OAR (NCA4)

52. OP (climate communities resiliency)

Cardin

53. OW [OCFO follow up review] (WIFIA)

54. OW [OCFO follow up review] (WIFIA)

Sanders

55. OLEM (VT Brownfields)

56. OW [R1 follow up review] (Lake Champlain TMDL)

57. OAR (cost benefit rule)

58. OW (401)

59. OAR (SAFE)

60. OAR (air quality)

61. OW (PFAS)

62. OCSPP (TSCA preemption)

63. OAR (ethylene oxide)

64. OW [OGC follow up review] (perchlorate)

Whitehouse

65. Oversight (Marathon) [KK suggests OCIR lead 65-70]

66. Oversight (Marathon)

67. Oversight (Marathon)

68. Oversight (Marathon)

69. Oversight (Marathon)

70. Oversight (Marathon)

71. Oversight (Marathon)

72. Oversight [ORD follow up review] (Steve Milloy/Science Rule)

73. Oversight [ORD follow up review] (studies that link air pollution and COVID-19)

74. ORD (SAB draft report on science rule)

75. ORD [OAR follow up review] (science transparency)

76. OAR (California FOIA requests for SAFE data).

Merkley

77. OCSPP (Asbestos)

78. OCSPP (Asbestos)

79. OCSPP (Asbestos)

80. OCSPP (Asbestos)

81. OCSPP (Asbestos)

82. OAR (air monitoring)

Gillibrand

83. R2/ORD/OLEM (PFAS Norlite) [R2/ORD needs to draft response on our efforts re NY-Norlite facility to provide context and then ORD/OLEM draft responses to the actual questions]

84. OLEM (interim guidance on disposal/Cohoes moratorium)

85. R2/ORD (Cohoes testing)

86. OAR (indoor air COVID-19)

87. OAR (indoor air COVID-19)

Booker

88. OAR (PM proposal EJ analysis)

89. OCSPP (TCE)

90. OLEM (Superfund funding for economic boost)

Markey

91. OW (perchlorate)

92. OCSPP (TCE)

93. OAR [AO/OPA/OCIR follow up review] (National Climate Assessment)

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